

REMARKS

The Pending Claims

Claims 28 and 29 are canceled herein without prejudice. Applicant reserves the right to claim the subject matter of claims 28 and 29 in continuing applications. Claims 1-25 and 30-32 are currently pending. Claim 1 is amended herein. Support for the amendment is found throughout the specification at, *inter alia* §0059, 0141 and 0142 and from the original claims 28 and 29. No new matter is added by this amendment. No claim is currently allowed.

I. Rejection under 35 U.S.C. § 102

Claims 1-20, 22-25, and 28 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Laugharn *et al* (U.S. Patent No. 6,120,985; hereinafter “Laugharn”). Applicant respectfully disagrees.

The Examiner asserts that Laugharn teaches a method of isolating nucleic acid and proteins from each other in a sample and the method include providing a solid phase material in a cartridge and further teaches that cartridge include multiple compartments containing different solid phase material, thus teaching a plurality of solid supports.

Laugharn fails to anticipate the claimed methods as it fails to set forth each and every element of the methods. The test for anticipation is one of strict identity. *Trintec Industries, Inc. v. Top-U.S.A. Corp.*, 63 U.S.P.Q.2d 1597 (Fed. Cir.2002). “A claim is anticipated **only** if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” MPEP § 2131 (citation omitted (emphasis added)). Laugharn fails to fulfill this standard.

The claimed methods are drawn to isolation of nucleic acid and proteins using magnetic particles and magnetic aggregation. *See, e.g.*, Specifications at §§ 0141 to 0142. In contrast Laugharn discloses methods for isolation and purification of biological materials, involving subjecting a sample maintained at a subzero temperature to high pressure to lyse the cells (Abstract) followed by the separation of the cellular component utilizing the discovery that hyperbaric, hydrostatic pressure reversibly alters the partitioning of biomolecules between certain adsorbed and solvated phases relative to partitioning at ambient pressure (column 1, line 50). The biomolecules are moved within a pressure-modulation apparatus by electrophoretic or

electroosmotic means (column 2, lines 31-44) or by pressure-induced flow (column 15, lines 28-38). Laugharn is silent regarding method of isolating nucleic acids in a sequence independent manner using magnetic particles and magnetic aggregation and also about isolating proteins using only chromatographic interactions onto magnetic particles followed by particle isolation using magnetic aggregation. As Laugharn fails to teach these elements, it fails to anticipate the claimed methods.

For at least these reasons, Applicant respectfully requests that the rejections of claims 1-20, 22-25, and 28 under 35 U.S.C. § 102 be withdrawn.

II. Rejection under 35 U.S.C. § 103

Claims 1, 21, and 28-29 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Laugharn *et al* (USPN 6,120,985; hereinafter “Laugharn”). In view of Smith *et al* (USPN 6,310,199; hereinafter “Smith”).

Claims 1, 28-29 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Laugharn *et al* (USPN 6,120,985; hereinafter “Laugharn”) in view of Olsvik *et al* (WO92/17609 hereinafter “Olsvik”).

Applicant respectfully submits that none of the cited combinations of references render the claimed invention *prima facie* obvious. First the cited combination must teach or suggest each and every limitation to the claimed invention(s). Then, the obviousness analysis under 35 U.S.C. § 103(a) requires the consideration of the scope and the content of the prior art, the level of skill in the relevant art, and the differences between the prior art and the claimed subject matter. *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966). Applicants note that if a modification changes the principle of operation of a reference, then there cannot be said that a reasonable expectation of success exists.

According to MPEP § 706.02(j), for a claim to be obvious, there must be a) a suggestion or motivation to combine reference teachings, b) a reasonable expectation of success, and c) the references must teach all of the claim limitations, *In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991).

As discussed above, Laugharn does not disclose the use of magnetic particles for the isolation of nucleic acids and proteins. The cited references Smith and Olsvik disclose the use of magnetic particles for the isolation of nucleic acid and protein. However, the methods disclosed by Laugharn involve the use of a cryobaric apparatus that is used for Cryobaric cell Lysis – see column 15, lines 51-59. The cryobaric apparatus of Laugharn is not suitable for use with magnetic bead-based separation. In column 17 from line 43 to line 62 Laugharn discloses the electrophoretic transfer of the molecules to be isolated from the cryobaric chamber to the cryobaric reservoir and also discloses a membrane inserted between the two to prevent macroscopic particles from collecting into the collection reservoir. One skilled in the art would not be motivated to combine the use of the magnetic beads of Smith or Osvik with the apparatus of Laugharn because the apparatus of Laugharn does not allow movement of particles within the apparatus.

In view of the above, none of the cited references alone or in combination teach or suggest the binding of target proteins to solid supports having a surface capable of effecting a chromatographic interaction wherein the solid supports to which nucleic acids components are bound are distinct from the solid supports to which protein components are bound, and wherein the solid support are in the form of magnetic particles as recited in independent claim 1.

Accordingly, Applicant requests that the rejections of claims 1 to 25 under 35 U.S.C. § 103 be withdrawn.

CONCLUSION

In light of the above amendments and remarks, reconsideration and withdrawal of the outstanding objections and rejections are respectfully requested. All amendments are made in a good faith effort to advance the prosecution on the merits. Applicant respectfully submits that no amendments have been made to the pending claims for the purpose of overcoming any prior art rejections that would restrict the literal scope of the claims or equivalents thereof. Applicant reserves the right to subsequently take up prosecution of the claims originally filed in this application in continuation, continuation-in-part, and/or divisional applications.

The Examiner is encouraged to call the undersigned should any further action be required for allowance.

Respectfully submitted,

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